

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

)
)
) MDL NO. 1456
) Civil Action No. 01-12257-PBS
)

THIS DOCUMENT RELATES TO
01-CV-12257-PBS AND 01-CV-339

) Hon. Patti B. Saris
)
)
)

**TRACK 1 DEFENDANTS'
REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS'
MOTION TO STRIKE THE DECLARATION OF RAYMOND S. HARTMAN**

Defendants moved to strike Dr. Hartman's declaration because the fundamental flaws in his "expectation" methodology render it an unreliable basis for determining class-wide injury, causation and liability. Defendants identified specific flaws in Hartman's methodology: (1) it assumes class-wide injury and liability rather than proving it; (2) it purports to determine injury and causation based on class members' "expectation" of the spread, yet ignores what each Class member's actual expectation really was; (3) it relies on individual inquiries at the damages phase to determine threshold questions of liability; (4) it fails to reflect in the baseline for the "spread" (Hartman's "ASP") "who gets the rebate" – providers or class members; (5) it improperly calculates ASPs in a way that ignores distinctions between customer classes; and (6) it cannot account for the trade-offs that occur in the complex web of separately negotiated contracts that govern these transactions.

Hartman's rebuttal submissions – despite their prolixity – fail to address those flaws, and instead focus on issues that defendants have not raised. Defendants do not dispute that AWP is used as a benchmark in many contracts. But that is the beginning of the analysis, not the end of it, and that fact alone does not demonstrate that any class member has been injured. Hartman's methodology remains fundamentally flawed and it should be stricken.

I. Plaintiffs Acknowledge In Their Serial Motions To Strike That The Court Should Strictly Scrutinize Expert Testimony Under Daubert At This Stage.

Plaintiffs have based their certification motion on Hartman's methodology; if that methodology is defective, then plaintiffs' motion cannot survive. Yet plaintiffs contend that Hartman's submissions should draw just a cursory look from the Court at the certification stage. (Pl. Opp. at 1-3.) Plaintiffs advocate "limited" *Daubert* review so that the Court does not engage in "inappropriate consideration of the merits of plaintiffs' claims." (*Id.* at 2.) But the Court need not address the merits to decide defendants' motion, because the motion is directed solely at Hartman's methodology. The issue for the Court to decide is whether Hartman's "expectation methodology" offers a reliable method for proving class-wide injury, causation and liability.

The motion does not challenge plaintiffs' allegations or address Hartman's conclusions regarding the merits of plaintiffs' claims.

Other district courts have analyzed proposed expert methodologies under *Daubert* at the certification stage without treading on plaintiffs' claims on the merits. (*See* Def. Mem. in Supp. of Mot. to Strike Hartman at 5-6 (citing cases).) The authorities that plaintiffs cite in support of "limited" *Daubert* review at the certification stage (Pl. Opp. at 1-2 and nn.2-3) allow scrutiny of an expert's methodology, so long as a Court reserves judgment on the weight to be given to the expert's conclusions.¹ Defendants' motion to strike Hartman does not ask the Court to assess his conclusions. Because defendants' motion is directed at whether Hartman's methodology is reliable and not at the merits of plaintiffs' claims, the rationale that plaintiffs invoke for conducting "limited" *Daubert* review of Hartman's methodology is not relevant here.

Plaintiffs' argument against *Daubert* review at the certification stage is also severely undermined by the three *Daubert* motions that plaintiffs recently filed to strike defendants' experts.² Plaintiffs base each of their motions on cases from this circuit that scrutinized expert testimony under full *Daubert* review.³ Indeed, the grounds that plaintiffs invoke for striking defendants' experts – knowledge, relevance, credibility, qualifications – could *only* be reached if the Court conducts a full *Daubert* review, a point that plaintiffs make in their opposition brief.

¹ *See Nichols v. SmithKline Beecham Corp.*, 2003 WL 302352 (E.D. Pa. Jan. 29, 2003) (at the certification stage "the Court will examine whether [plaintiffs' expert] has identified a generally accepted methodology for determining impact which is applicable to the class, whether this methodology uses evidence common to all class members, and whether his opinion has probative value"); *In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124 (2d Cir. 2001); *In re Sumitomo Copper Litig.*, 182 F.R.D. 85 (S.D.N.Y. 1998); *In re Disposable Contact Lens Antitrust Litig.*, 170 F.R.D. 524 (M.D. Fla. 1996).

² *See* "Class Plaintiffs' Memorandum In Support Of Their Motion To Strike Portions Of The Declaration Of Robert P. Navarro" ("Pl. Navarro Mem."); "Class Plaintiffs' Memorandum In Support Of Their Motion To Strike Declaration Of Eric M. Gaier, Ph.D" ("Pl. Gaier Mem."); Class Plaintiffs' Memorandum In Support Of Their Motion To Strike The Declaration Of Steven J. Young" ("Pl. Young Mem.").

³ *See, e.g.*, Pl. Navarro Mem. 4-5; Pl. Gaier Mem. 4-5, 10; Pl. Young Mem. 4 (citing *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77 (1st Cir. 1998); *Polaino v. Bayer Corp.*, 122 F. Supp. 2d 63 (D. Mass. 2000); *Smith v. Gen. Elec. Co.*, 2004 WL 870832 (D. Mass. Apr. 23, 2004)).

(Pl. Opp. at 5) (explaining that judgments such as expert qualifications, knowledge, and relevance of expert testimony fall under “the stricter *Daubert* standard”).⁴

Having cast Hartman’s methodology as the lynchpin of their certification motion, and having made the tactical decision to strike defendants’ experts on grounds only reached during full *Daubert* review, plaintiffs’ effort to shield their own expert’s methodology from scrutiny under *Daubert* rings hollow. But as a practical matter, the Court need not choose between “full” and “limited” *Daubert* review. The defects in Hartman’s methodology are so fundamental and disabling that they warrant striking his opinion under either standard.

II. Hartman’s Created-For-This-Litigation “Expectation” Methodology Has Nothing In Common With The Models He Or Other Experts Have Employed In Prior Cases.

Plaintiffs assert that Hartman’s expectation methodology is an unremarkable adaptation of methodologies that he has used before, and that similar methodologies have routinely been accepted in other class actions. Both assertions are wrong.

A. Hartman’s Methodology In This Case Bears No Resemblance To The Methodologies He Has Used In Prior Cases.

Plaintiffs first contend that Hartman’s methodology is reliable because Hartman has used “similar methodologies” in prior cases brought against pharmaceutical companies, including “three in which the Classes were certified.” (Pl. Opp. at 4, 7; Hartman’s White Reb. ¶ 13 and n.9.) But apart from the fact that they involved the pharmaceutical industry, Hartman’s economic models in those three prior cases – *Cipro*, *Relafen* and *Terazosin*⁵ – have little in common with the methodology that Hartman has asked this Court to accept. As Hartman

⁴ In support of their effort to strike one defense expert, plaintiffs even quote from authority that applied full *Daubert* review at the certification stage – only to contend elsewhere that the very same authority should not apply to Hartman because it is “unpersuasive.” Compare Pl. Gaier Mem. at 5 (quoting from *Yapp v. Union Pac. R.R. Co.*, 301 F. Supp. 2d 1030 (E.D. Mo. 2004), with Pl. Opp. at 3 n.5 (asserting that “Defendants’ principal authorities are not persuasive,” and citing *Yapp*). Plaintiffs’ “heads we win tails you lose” tactic belies their statement in one of their motion papers (but not the others) that “limited” *Daubert* review is “appropriate.” (Pl. Gaier Mem. at 4.)

⁵ Decisions discussing those methodologies are reported at *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672 (S.D. Fla. 2004); *In re Relafen Antitrust Litig.*, 221 F.R.D. 260 (D. Mass. 2004); and *Cipro Cases I and II*, 2003 WL 23005275 (Cal. Super. Nov. 25, 2003), *aff’d*, 121 Cal. App. 4th 402 (Cal. Ct. App. 2004).

admitted at his deposition, no one has ever used his “expectation yardstick” methodology before. (Hartman Dep. Tr. 47-55, 260-61, 338.)

Cipro, *Relafen* and *Terazosin* were antitrust suits that followed on the heels of judicial findings that the defendant had improperly obtained or extended a patent for a single chemical compound. In each case plaintiffs alleged that they were harmed because the manufacturer used the ill-gotten patent protection to unlawfully delay the market entry of a generic competitor. Thus, each case required expert testimony on the effect of generic competition on the market share of a branded drug.

Hartman therefore addressed a different question in those prior cases. His assignment was to determine how quickly consumers switch from branded drugs when a generic alternative enters the market and to assess the “but for” prices that would have prevailed had generic competition not been thwarted. To answer that question, Hartman developed estimates of generic market penetration. He then attempted to assess how purchasers are affected when the market entry of a generic substitute is delayed. Based on his analyses, Hartman proffered economic models that attempted to (i) determine aggregate “antitrust impact” of delayed generic competition with respect to the market for a single drug, and (ii) estimate the aggregate antitrust damages for purchasers of that drug.

While Hartman developed a “but for” model in those cases, none of those cases involved (a) the use of subjective expectations to develop yardsticks; (b) the averaging of expectations to eliminate individual variations; or (c) the construction of an artificial benchmark, such as ASPs cutting across customer classes, in order to inflate the differences between subjective expectations and actual prices. All of that is new and has been developed specifically for this case. (Hartman Dep. Tr. 54-55.) It bears no resemblance to Hartman’s efforts to analyze the pace and effect of generic entry, which Hartman acknowledges was the purpose of the generic penetration model he used in other cases. *See, e.g., Cipro*, 121 Cal. App. 4th at 408 (“Hartman described the formula in detail in his declaration and explained that the formula was widely used and accepted in scientific analysis of the penetration of generic drugs into the market”).

Indeed, to the extent that Hartman has attempted to develop “but for” models in other cases to determine *individual* injury, his methodology has been rejected. In the *Relafen* litigation, Judge Young declined to certify classes of end payors from several states with “indirect purchaser” antitrust statutes that require a clear showing of *individual injury to each consumer*. Rejecting Hartman’s effort to make such a showing, Judge Young concluded that “none of Dr. Hartman’s proposed methods demonstrates individual impact to members of the end payor plaintiffs’ classes.” *In re Relafen*, 221 F.R.D. at 282.

Hartman’s effort to divine individual injury in this case is no more successful than it was in *Relafen*. Because his “expectation” methodology analyzes class-wide injury and liability based on a uniform average “market expectation,” Hartman’s methodology will find impact even for purchasers whose expectations fell within Hartman’s “yardsticks” and who therefore were not injured at all.

B. No Other Court Has Accepted This Type Of Methodology.

Plaintiffs also contend that “courts regularly accept the base methodology employed by Dr. Hartman here,” and that “Dr. Hartman’s methodology starts and ends with unexceptional and widely-used economic tools, including data collection, econometrics, algebra and mathematics.” (Pl. Opp. at 3.) Plaintiffs’ authorities do not support this assertion.

None of the seven other cases that plaintiffs cite (Pl. Opp. at 4, 7-8) involved an economic methodology that remotely resembles Hartman’s or that used a similar type of “yardstick.” Six of those seven cases were antitrust price fixing cases where common antitrust impact is presumed;⁶ the seventh was an antitrust monopoly case involving an airline merger.⁷

⁶ *In re Potash Antitrust Litig.*, 159 F.R.D. 682 (D. Minn. 1995); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297 (E.D. Mich. 2001); *In re Commercial Tissue Prods. Antitrust Litig.*, 183 F.R.D. 589 (N.D. Fla. 1998); *In re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. 493 (S.D.N.Y. 1993); *City of Tuscaloosa v. Harcross Chems., Inc.*, 158 F.R.D. 548 (11th Cir. 1998); *Ohio ex rel. v. Louis Trauth Dairy, Inc.*, 925 F. Supp. 1247 (S.D. Ohio 1996).

⁷ *Midwestern Machinery v. Northwest Airlines*, 211 F.R.D. 493 (D. Minn. 2001). The “benchmarking” approach that plaintiffs highlight (Pl. Opp. at 4 n.7) was used for estimating damages, not for determining injury or causation.

None of those methodologies attempted to determine class-wide liability and injury from an alleged fraud based on class members' subjective expectations, much less based on a single, uniform "market expectation" for the entire class. Two of those cases did discuss economic methodologies that referred to a "yardstick," but the "yardstick" was used only as a way to estimate aggregate antitrust price fixing damages, not for determining injury or causation, and not for an alleged fraud.⁸ Hartman's methodology for assessing class-wide injury and causation using as his "yardstick" of the average "market expectation" of the class has no precedent in any reported decisions.

Defendants' motion does not challenge the validity of statistics, econometrics, regression analysis, mathematics, or any other standard economic tool, as plaintiffs imply. (Pl. Opp. at 3-4.) There are certainly cases, moreover, in which economists have used a "yardstick" as part of their damages methodology in antitrust cases. But if that generic term alone can confer reliability, however, then *Daubert* is a dead letter.

III. Plaintiffs Fail To Rebut The Flaws Identified In Defendant's Motion.

A. Hartman's Methodology Does Not Try To Prove Class-Wide Injury and Causation; It Assumes It.

Plaintiffs deny that Hartman's methodology is built on a tautology because "the only matters that Dr. Hartman assumes are the truth of the complaint's allegations of AWP inflation." (Pl. Opp. at 8.) According to plaintiffs, "[w]hat Dr. Hartman has not assumed is that class members have been adversely impacted by the AWP inflation. Instead, Dr. Hartman has *analyzed* whether that could be determined by employing well-accepted economic methodology." (*Id.* at 9) (emphasis in the original.) But Hartman's rebuttal submissions make clear that he is assuming the result he purports to analyze:

⁸ Cf. *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. at 321; *In re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. at 521.

- “If a Class member referenced the allegedly-inflated AWP to set reimbursement rates for a particular drug, that Class member was obviously impacted.” (Hartman Rebuttal Declaration at 4.)
- “[A]ll members of the proposed Classes were impacted by the fraud precisely because they negotiated their reimbursement contracts and calculated their reimbursement rates with reference to artificially-inflated AWPs.” (*Id.* at ¶ 15(b).)
- “[T]he assumption of AWP inflation implies impact upon Class members” (Hartman Rebuttal to Dr. White at 8.)
- “[H]ow is it possible that Class members are not impacted by the alleged violations? The quantum of impact remains to be determined, but the fact of impact certainly does not. . . . the economic impacts involved common injury and damages” (*Id.* at 4-5.)

As Hartman testified at his deposition: “I don’t need econometrics to tell me if the allegation is that the AWPs of those drugs have been inflated [there has been impact] – it is a matter of English.” (Hartman Dep. Tr. 439.)

Hartman has not analyzed whether individual injury can be shown on a class-wide basis. He has assumed it. He has not simply assumed that plaintiffs’ allegations about defendants’ conduct are true; he has also assumed that plaintiffs’ allegations of causation are true as well. Consequently, under Hartman’s methodology, all members of the Class by definition have been injured. But class-wide injury, based on common evidence, is what his methodology is supposed to *prove*.

The Supreme Court has observed that “nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” *Gen. Elec. v. Joiner*, 522 U.S. 136, 146 (1997). Hartman’s methodology falls squarely in this category.

B. Hartman Cannot Reliably Determine Whether Specific Payers Were Injured By Using Class-Wide “Average Expectations” About The Relationship Between AWP and ASP.

Our opening brief noted that a methodology that purports to determine class-wide injury and causation based on the “average expectation” of a sample of class members is no more

reliable than giving 1,000 drivers a speeding ticket based on the “average speed” of a dozen of them. Hartman’s use of averages to determine whether there are individual issues assumes away the very question he is supposed to answer.⁹ Plaintiffs’ rebuttal submissions do not respond to this criticism of Hartman’s methodology.

The authority that plaintiffs cite in support of Hartman’s “expectation methodology” does not remotely imply that class-wide causation and injury can be assessed in this manner. None of the four antitrust cases that plaintiffs cite (Pl. Opp. 13-15)¹⁰ dealt with measuring expectations, much the less whether a class may be certified based on a methodology using an “average expectation” that ignores the actual expectations of class members.¹¹ The two opinions by Judge Stearns that plaintiffs rely on (Pl. Opp. at 15) both highlight that the unreliability of Hartman’s methodology as a basis for certifying the class.¹²

⁹ If the “actual spread” for a drug was 20%, and a payer expected it was higher, then according to the plaintiffs’ allegations that payer *was not injured*. But Hartman’s methodology would discard this payer’s actual expectations and substitute a single “average expectation” for all payers. Thus, if the “average expectation” of a sample of payers for that drug turns out to be lower than 20% instead of higher, then the payer who was not injured *would be found to be injured* under Hartman’s liability-by-proxy methodology.

¹⁰ *In re Commercial Tissue Prods. Antitrust Litig.*, 183 F.R.D. 589, 595 (N.D. Fla. 1998); *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672 (S.D. Fla. 2004); *Midwestern Mach. v. Northwest Airlines*, 211 F.R.D. 562 (D. Minn. 2001); *In re Indus. Diamonds Antitrust Litig.*, 167 F.R.D. 374 (S.D.N.Y. 1996).

¹¹ Plaintiffs’ brief reproduces a lengthy quote from *In re Commercial Tissue Prods. Antitrust Litig.* (Pl. Opp. 13-14) that discounts “considerable individual variety in pricing because of individual price negotiations” as an obstacle to class certification. That case is distinguishable because it involved a horizontal price fixing conspiracy. As numerous courts have noted, “because the gravamen of a price-fixing claim is that the price in a given market is artificially high, there is a presumption that an illegal price-fixing scheme impacts upon all purchasers of a price-fixed product in a conspiratorially affected market.” *In re Potash*, 149 F.R.D. at 695 (citing and quoting cases to similar effect). Plaintiffs’ featured quote has no application beyond the antitrust price fixing context.

¹² See *Smith v. Gen. Elec. Co.*, 2004 WL 870832 at *4 (D. Mass. 2000) (cautioning that the sponsor of expert evidence must “show that the expert’s conclusion has been arrived at in a scientifically sound and methodologically reliable fashion”) (quoting *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998)); *Polaino v. Bayer Corp.*, 122 F. Supp. 2d 63, 67 (D. Mass. 2000).

C. Hartman Continues To Defer Individual Determinations Of Critical Issues To The Damage Phase.

As defendants demonstrated in their submissions and the tutorial, the question of who gets the rebate – the PBM or the class member – can be critical to determining whether individual class members have been injured. Hartman responds that he intends to postpone this question of injury and causation until damages phase. (Hartman Rebuttal Decl. ¶ 60.) Clearly, a methodology that cannot assess injury or causation until an individualized inquiry is conducted at the damages phase is not capable of determining class-wide injury based on common proof.

Defendants' opening papers also showed that Hartman inflates the spread by using sales to customer classes such as hospitals – which get steeper discounts than the pharmacies who provide drugs to the purported class – to establish ASPs, and in this regard Hartman's methodology has been rejected by plaintiffs' other expert, Dr. Schondelmeyer. Hartman makes no response to this defect other than to defer it to a later date.

D. Hartman's Approach To Trade-Offs Is To Assume Them Away.

In our opening papers, we pointed out that Hartman's methodology fails to account for the trade-offs between drug price and other contract terms. In his rebuttal, he evades this issue by asserting that "if it is proved that the full extent of this fraudulent spread was understood by a class member and taken as necessary to subsidize other services . . . I understand that impact and damages occur as a matter of law." In other words, Hartman has no methodology for dealing with well-informed class members. (Hartman Rebuttal Decl. ¶ 73.)

CONCLUSION

For the reasons set forth above, as well as in defendants' opening memorandum, Dr. Hartman's declaration should be stricken.

Respectfully submitted,
THE TRACK 1 DEFENDANTS

By: /s/ Jessica V. Barnett
Nicholas C. Theodorou (BBO #496730)
Jessica V. Barnett (BBO #650535)
Foley Hoag LLP
155 Seaport Boulevard
Boston, MA 02110

D. Scott Wise
Michael Flynn
Kimberley Harris
Davis Polk & Wardwell
450 Lexington Avenue
New York, NY 10017

Attorneys for AstraZeneca Pharmaceuticals LP

Steven M. Edwards
Lyndon M. Tretter
Hogan & Hartson, LLP
875 Third Avenue
New York, NY 10022

*Attorneys for the Bristol-Myers Squibb Co., Oncology
Therapeutics Network Corp., and Apothecon, Inc.*

Mark H. Lynch
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-7566

Frederick G. Herold
Dechert LLP
975 Page Mill Road
Palo Alto, CA 94304-1013

Geoffrey E. Hobart
Holland & Knight LLP
10 St. James Ave.
Boston, MA 02116

*Attorneys for SmithKlineBeecham Corp.
d/b/a GlaxoSmithKline*

William F. Cavanaugh, Jr.
Andrew D. Schau
Erik Haas
Patterson, Belknap, Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036 6710

Attorneys for the Johnson and Johnson Group

John T. Montgomery
Steven Kaufman
Ropes & Gray LLP
One International Place
Boston, MA 02110

*Attorneys for Schering-Plough Corp. and Warrick
Pharmaceuticals Corp.*

Dated: January 21, 2005

CERTIFICATE OF SERVICE

I certify that on January 21, 2005, a true and correct copy of the foregoing Track One Defendants' Reply Memorandum in Support of Defendants' Motion to Strike the Declaration of Raymond S. Hartman was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to Verilaw Technologies for posting and notification to all parties.

/s/ Jessica V. Barnett

Jessica V. Barnett